DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 24, 2014

Cork Medical Products LLC
% Mr. Jon D. Speer
Creo Quality, LLC
P.O. Box 1784
Martinsville, Indiana 46151

Re: K140022
Trade/Device Name: Cork Medical Products Nisus Negative Pressure Wound Therapy System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: September 24, 2014
Received: September 26, 2014

Dear Mr. Speer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K140022

Device Name
Cork Medical Products Nisus Negative Pressure Wound Therapy System

Indications for Use *(Describe)*
The Cork Medical Products Nisus Negative Pressure Wound Therapy System is indicated for use in patients who would benefit from negative pressure wound therapy particularly as the device may promote wound healing by the removal of excess exudates, infectious material, and tissue debris.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

807.92(c)

SPONSOR 807.92(a)(1)

Company Name: Cork Medical Products
Company Address: 8050 Castleway Drive
Indianapolis, IN 46250

Telephone: 317-537-2000
Fax: 844-269-8439
Contact Person: Jon D. Speer
Date Prepared: September 24, 2014

DEVICE NAME 807.92(a)(2)

Trade Name: Cork Medical Products Nisus Negative Pressure Wound Therapy System
Common / Usual Name: Cork NPWT System
Classification Name: Negative Pressure Wound Therapy Powered Suction Pump and Accessories
Regulation Number: 21 CFR 878.4780
Product Code: OMP
Device Class: Class II

PREDICATE DEVICE 807.92(a)(3)

Company	Brand Name	510(k) Number
Genadyne Biotechnologies, Inc.	A4 Wound Dressing Vacuum System Kit	K082676
Genadyne Biotechnologies, Inc.	A4-XLR8 Foam Dressing	K092992

DEVICE DESCRIPTION 807.92(a)(4)

Cork Medical Products has developed a negative pressure wound therapy system. The Cork Medical Products Nisus Negative Pressure Wound Therapy System is indicated for use in patients who would benefit from negative pressure wound therapy particularly as the device

may promote wound healing by the removal of excess exudates, infectious material, and tissue debris.

The components included within the Cork NPWT System are:

- Nisus Negative Pressure Wound Therapy Pump
- Nisus NPWT Canister 250-mL
- Nisus Pump Battery Charger
- Cork Medical Products NPWT Wound Dressing Kit – Medium
- Cork Medical Products NPWT Wound Dressing Kit – Large

DEVICE INTENDED USE 807.92(a)(5)

Indications for Use

The Cork Medical Products Nisus Negative Pressure Wound Therapy System is indicated for use in patients who would benefit from negative pressure wound therapy particularly as the device may promote wound healing by the removal of excess exudates, infectious material, and tissue debris.

Physician Orders

Caution: Federal Law (USA) restricts this device to sale by or on the order of a licensed physician.

Use of the Nisus NPWT System must be prescribed by a physician per the stated indications for use. As a condition of use, the Nisus NPWT System should only be used by qualified and authorized personnel. The user must have the necessary knowledge of the specific medical application for which negative pressure wound therapy is being used.

Prior to placement of the Nisus NPWT System, the medical professional treating the wound must assess how to best use the system for an individual wound. It is important to carefully assess the wound and patient to ensure clinical indications for negative pressure wound therapy are met.

All orders should include:

- Wound location, size, and type
- Dressing kit type
- Negative pressure settings
- Frequency of dressing changes
- Secondary dressings

User

The Nisus NPWT System is designed for use by licensed healthcare professionals only. Patients may be trained to perform some limited functions, but the keypad and device menus are locked by the healthcare professional to prevent patient from changing the setting prescribed by the physician.

NOTE: Patient functions are limited to power on / off, respond to any alarm conditions, and navigating to troubleshooting (should an alarm occur).

Use Environment

Cork Medical Products Nisus NPWT System is designed for the following environmental conditions:

Operating Temperature: 18°C to 34°C (65°F to 94°F)
Operating Relative Humidity: 10% - 95%
Operating Pressure: 700-hPA – 1060-hPA (10.15-atm – 15.37-atm) atmospheric pressure

PREDICATE PRODUCT COMPARISON TABLE 807.92(a)(6)

	New Device	Predicate Device
Company	Cork Medical Products	Genadyne Biotechnologies, Inc.
Device Name	Nisus Negative Pressure Wound Therapy System	A4 Wound Dressing Vacuum System Kit & A4-XLR8 Foam Dressing
510(k) Number	K140022	K082676 K092992
Regulation Number / Product Code	21 CFR 878.4780 / OMP	21 CFR 878.4780 / OMP
Indications for Use	The Cork Medical Products Nisus Negative Pressure Wound Therapy System is indicated for use in patients who would benefit from negative pressure wound therapy particularly as the device may promote wound healing by the removal of excess exudates, infectious material, and tissue debris.	K082676: The Genadyne A4 Wound Vacuum System is indicated for use in patients who would benefit from negative pressure wound therapy particularly as the device may promote wound healing by the removal of excess exudates, infectious material and tissue debris. (NOTE: K082676 includes accessory kit comprised of gauze, transparent film dressing, and silicone flat drain.) K092992: Genadyne A4-XLR8 Foam Dressing is intended to be used in conjunction with the Genadyne A4 Wound Vacuum System (K082676) to deliver negative pressure wound therapy to the wound. Genadyne A4 Wound Vacuum System is indicated for patients who would benefit from a suction device, particularly as the device may promote wound healing by the removal of excess exudates, infectious material and tissues debris.
Contraindications	The Nisus NPWT System is contraindicated for patients with: • Necrotic tissue with eschar present	The Genadyne A4 is contraindicated in the presence of: • Necrotic tissue • Untreated osteomyelitis • Malignancy (with the exception

	New Device	Predicate Device
	• Untreated osteomyelitis Malignancy in the wound • Non-enteric and unexplored fistulas Do not place dressing directly in contact with: • Exposed blood vessels • Anastomotic sites • Organs • Nerves	to enhance quality of life) • Untreated malnutrition • Exposed arteries, veins, or organs
Pump - Technical Data		
Suction Capacity	4 liters / minute	5 liters / minute
Maximum Vacuum Pressure	220-mmHg	230-mmHg
Power Requirements	18 VDC, 2A	24 VDC, 1A
Battery Type	Li-ion	Ni-MH
Dimensions	151 x 108 x 71-mm (~6 x 4.3 x 2.8-inches)	200 x 180 x 80-mm (~7.9 x 7.1 x 3.1-inches)
Weight	0.575-kg (~1.27-lb)	1.36-kg (~3-lb)
Reusable	Yes	Yes
Sterile	Non-sterile	Non-sterile
Compliance	IEC 60601-1:2005, 3rd Edition (AAMI ES 60601-1, CAN/CSA C22.2 No. 60601-1-08, EN 60601-1) IEC 60601-1-2:2007 IEC 60601-1-6:2010 / IEC 62366:2010 IEC 60601-1-11:2010	UL 60601-1 CAN/CSA C22.2 No. 601-1-M90
Storage & Shipping Conditions	-25°C (-13°F) without relative humidity control to 44°C (111°F) up to 93% relative humidity (non-condensing)	-18°C to +43°C (0°F to 110°F) Relative Humidity 10% to 95% 700 – 1060 mbar Atmospheric pressure
Environmental Conditions	Operating Temperature: 18°C to 34°C (65°F to 94°F) Operating Relative Humidity: 10% - 95% Operating Pressure: 700-hPA – 1060-hPA (10.15-atm – 15.37-atm) atmospheric pressure	18°C to 34°C (65°F to 94°F) Relative Humidity 10% to 95% 700 – 1060 mbar Atmospheric pressure
Accessories		
Canisters	250-mL disposable canister Canister includes hydrophobic membrane filter and liquid solidifier	800-mL disposable canister with a build-in hydrophobic shut off filter for overflow protection
Wound Dressing Kit	Wound Foam: Reticulated polyether based polyurethane foam (A30M) Wound Drape: Transparent polyurethane film with adhesive backing Port Pad Assembly: Silicone port pad, Port Pad Skirt (Transparent polyurethane film with adhesive	K082676: Non-adherent gauze Anti-microbial gauze Transparent film dressing Silicone flat drain K092992 Reticulated polyether based

	New Device	Predicate Device
	backing), Drainage tubing, Luer connector, Pinch clamp Sterilized via Ethylene Oxide (cleared on K132004)	polyurethane foam (A30M) Individual kit components individually sterilized by Ethylene Oxide or Gamma Irradiation

NONCLINICAL TESTS 807.92(b)(1)

To ensure the Cork Medical Products Nisus Negative Pressure Wound Therapy System is substantially equivalent to the Genadyne A4 Wound Dressing Vacuum System Kit and A4-XLR8 Foam Dressing, Cork Medical conducted head to head performance testing. The head to head testing conducted:

- Continuous Mode Low Pressure (40-mmHg) Test
- Continuous Mode Typical Pressure (125-mmHg) Test
- Continuous Mode High Pressure (200-mmHg) Test
- Intermittent Mode Test (high pressure: 125-mmHg, low pressure: 40-mmHg)
- Leakage Alarm Test
- Canister Full Alarm Test
- Blockage Alarm Test
- Operating Parameter Test
- Storage & Shipping Parameter Test
- Canister Real-Time Aging
- Wound Dressing Kit Aging

Performance tests used simulated wound exudate. Pressure measurements were taken using a wound test bed fixture.

SUMMARY OF BIOCOMPATIBILITY COMPLIANCE TESTS 807.92(b)(1)

Of the items included within the Nisus NPWT System, biocompatibility is only applicable to the NPWT Wound Dressing Kits.

A Biocompatibility Risk Assessment was completed by Nelson Laboratories evaluating the biocompatibility of the entire Cork Medical Products Wound Dressing Kit.

Additional biocompatibility testing was performed on the wound foam and wound drape components, the patient contacting components, for surface device, breached or compromised surface, with a prolonged (24 hours – 30 day) contact per ISO 10993 testing standards. The specific biocompatibility testing performed on the wound foam and wound drape was:

- Cytotoxicity Test

- Intracuteneous Reactivity Test
- Sensitization Test

All biocompatibility test results were negative and passed the pre-defined test acceptance criteria.

Additional biocompatibility information has been provided for each of the individual components included in the Cork Medical Products Wound Dressing Kit, as follows:

- Wound Foam
  - Summary of ISO 10993 biocompatibility tests performed on material by UFP Technologies listed on A-30M specification.
  - Crest Foam A-30M MAF 1837- FDA Registration Certificate.
- Wound Drape & Port Pad Drape
  - Summary of ISO 10993 biocompatibility tests performed on DermaMed medical grade acrylic adhesive provided.
  - NOTE: The port pad drape is not in contact with the patient. Biocompatibility not required.
- Silicone Port Pad
  - This material is not in contact with the patient. Biocompatibility not required.
  - Wacker Silicones Elastosil® R 420/60 S.
- Port Pad tubing
  - This material is not in contact with the patient. Biocompatibility not required.
  - Dow Corning Silastic® RX-50 medical grade tubing.
- Luer connector – This material is not in contact with the patient. Biocompatibility not required.
- Pinch Clamp – This material is not in contact with the patient. Biocompatibility not required.

CLINICAL TESTS 807.92(b)(2)

No clinical testing required to support this 510(k) submission. No clinical testing has been performed.

SUBSTANTIAL EQUIVALENCE 807.92(b)(3)

The results of the nonclinical tests performed demonstrate the performance of the Cork Medical Products Nisus NPWT System is substantially equivalent to the performance of the predicate device, Genadyne A4 Wound Dressing Vacuum System Kit (K082676) and A4-XLR8 Foam Dressing (K092992). The results of the nonclinical tests and summary of biocompatibility compliance tests demonstrate the Cork Medical Products Wound Dressing Kit is safe.

To further establish substantial equivalence to the predicate device, Genadyne A4 Wound Dressing Vacuum System Kit and A4-XLR8 Foam Dressing, Cork Medical Products evaluated the indications for use, materials, technology, and product specifications for the components of the product. As a result of this analysis along with performance testing, Cork Medical has demonstrated substantial equivalence of the Cork Medical Products Nisus NPWT System for its indications for use.